

Attorney Docket No. 55411.000002  
Application No.: 09/242,657

### REMARKS

Claims 1-4, 6-11, 13-18, 21-23, 25 and 27 are indicated as rejected in the Office Action (and Claim 22 is indicated as allowed). Claims 1, 3, 4, 14, 16, 17, 18 and 21 are amended herein to clarify the subject matter of the invention.

The foregoing claim amendments are provided in the interest of furthering the prosecution of this application. No art has been cited against the claims and the claim amendments are not made for any reasons relating to patentability.

Basis for the claim amendments and newly added claims is found throughout the specification. In particular, basis for the amendment of claim 21 regarding the "cellular metabolism" can be found on page 2, line 24 and basis for the amendment of claims 1, 16 and 18 regarding the "at least two consensus sequences" are found on page 7, lines 17-28 and page 8, lines 11-13. Applicants believe that no new matter is submitted by these claim amendments. Accordingly, Applicants respectfully submit that the claim amendments should be entered.

### EXAMINER'S OBJECTIONS

The Examiner has objected to claims 1, 4 and 17 for various informalities. These claims have been amended to address the objections. Accordingly, Applicants respectfully request that the objections be withdrawn.

### REJECTION UNDER 35 U.S.C. § 112 SECOND PARAGRAPH

Claims 1-4, 6-11, 13-18, 21, 23, 25 and 27 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants submit that the claims prior to their amendment herein were definite because persons skilled in the art

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would have been readily able to ascertain the scope of the claimed invention. Nonetheless, Applicants amended their claims in an effort to expedite prosecution of the application. The amendments are intended to merely add consistency to certain portions of the claims, and they are not related to patentability of the claims. The amended claims continue to satisfy the definiteness requirements of 35 U.S.C. § 112, second paragraph.

In claims 1, 16 and 18, with regard to the Markush groups for the "at least two consensus sequences," the Examiner states that "it is unclear as the claims are written whether the recited Markush group includes embodiments where two upstream sequences are the two members of the Markush group that (sic) selected since the claims language as written appears to embrace multiple upstream elements. Office Action, pages 8 and 9. Applicants have amended the claims to clarify the invention consistent with the teachings in the specification. (see page 7, lines 17-28 and page 8, lines 11-13).

Claims 3, 14, 18 and 21 are rejected as being vague and indefinite for various reasons, such as lack of antecedent basis. Applicants have amended these claims to further clarify the subject matter.

In view of the foregoing amendments and remarks, Applicants respectfully request that the Examiner reconsider and withdraw the rejection. The Examiner is welcomed to contact the undersigned, if further clarification in the claims is believed to be required.

**REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**  
**(LACK OF ADEQUATE WRITTEN DESCRIPTION)**

Claims 1-4, 6-11, 13-15, 18, 23, 25 and 27 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in

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such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Examiner notes that Applicant's previous response argued limitations that were not in the claims, namely the limitation to a Markush group of organisms. Although Applicants respectfully submit that the claims prior to their amendment herein were described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, Applicants have amended their claims in an effort to expedite prosecution of the application. In particular, the claims are amended to include a Markush group of the specific microorganisms from the examples in the application. The amended claims continue to satisfy the written requirements of 35 U.S.C. § 112, first paragraph for the reasons set forth in applications previous response, which are repeated below.

As the Examiner has conceded, "[t]he instant specification describes consensus promoter sequences observed in a few different prokaryotic or eukaryotic microorganisms (e.g., *L. lactis*, *E. coli*, *S. cerevisiae*) and describes experiments wherein a range of different promoter activities in different microorganisms is obtained." Along these lines, Applicants wish to further point out the several examples showing the promoter sets for various *microorganisms*. For instance, Examples 1 and 2 on pages 17 to 27 of the specification specifically provide a set of promoter sequences for *L. lactis*, and Example 7 on pages 31-34 of the specification specifically provide a set of promoter sequences for *Saccharomyces cerevisiae*. Further examples are provided concerning other bacteria, such as *Bacillus subtilis*, *Pseudomonas* and *E. coli*, and various exemplary methodologies for constructing the promoter sequences in accordance with the claimed invention, as well.

The claims, as herein amended, now specifically recite organisms that the Examiner has indicated are supported by the examples of the specification. For

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example, claim 1 recites "a microorganism selected from the group consisting of lactic acid bacteria, Bacillus, E. coli, Pseudomonas and yeast." The claims also recite specific conserved sequences for bacteria and yeast.

Thus, the claims specifically recite structural characteristics (i.e., a double stranded DNA sequence, the sense strands of which comprise at least two conserved sequences identified in the specifically recited microorganisms and the conserved sequences are restricted to specific sequences for bacterium and yeast) and functional characteristics (i.e., a range of promoter activities in steps, each step changing the promoter activity by 50-100%) and that this is coupled with a "disclosed correlation between function and structure" (i.e., a set of sequences that optimizes expression of a gene in a selected microorganism). Therefore, there is more than adequate structural/functional basis for one of skill in the art to envision the claimed promoter sets.

For at least the foregoing reasons, a person of skill in the art would reasonably conclude Applicants were indeed in possession of the claimed invention. Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

#### **REQUEST FOR ALLOWANCE**

For at least the reasons detailed above, Applicants respectively submit that all of the claims in the application are patentable. Favorable consideration, entry of this amendment, and issuance of a notice of allowance are respectively requested.

In the event any issues remain, the Examiner is encouraged to contact applicants' representatives to resolve such issues in an expeditious manner, and place the application in condition for allowance.

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In the event any fees are incurred upon the filing of these documents, please charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

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